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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,165

11/16/2005

Masashi Komeda

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MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO

ATTN: PATENT INTAKE CUSTOMER NO. 35437

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BOSTON, MA 02111

EXAMINER

SINGH, SATYENDRA K

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,165	Applicant(s) KOMEDA ET AL.	
	Examiner SATYENDRA K. SINGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 30-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☒ Claim(s) 5,6 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants are advised that the assigned Examiner for this application has changed. All future communications regarding this application should be addressed to the new Examiner, Satyendra K. Singh, Art Unit 1657.

Claims 1-29 (elected invention of group I, with specie "catechin" from claim 23) have been examined on their merits in this office action.

Claims 30-60 (non-elected inventions of groups II-III) have been withdrawn from further consideration.

Election/Restrictions

Applicant's election of **group I** (claims 1-29; a pharmaceutical composition for protecting and preserving an organ, a tissue, or a cell) in the reply filed with the office on April 24th 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, and did not specifically point out if the election was made with or without traverse, the election has been treated as an **election without traverse** (MPEP § 818.03(a)).

Claims 1-29 (group I) have been examined herein to the extent they read on the composition comprising applicant's elected specie of "catechin" from claim 23.

Claim Objections

1. Claims 5 and 6 are objected to because of the following informalities: Claims recite the limitations "**wherein the administration is administered**", which is improper. Appropriate correction is required.

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2. Claim 25 is objected to because of the following informalities: claim has a typographical error in the term “epigallocatechin **gallate**”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiyoukiyuu (JP 2000-344602; IDS, citation no. C1, English abstract).

Claims are drawn to a pharmaceutical composition (for protecting and preserving an organ, a tissue, or a cell) comprising a purified polyphenol or a purified mixture of polyphenols (elected specie being “**catechin**”; see instant claim 1, in particular).

NOTE: Instant claims 3-21, as recited, are directed to either method steps of administration, or intended use of said composition, the limitations of which have not been given a patentable weight. If the claimed composition comprising catechin (i.e. comprising polyphenol, or a mixture of polyphenols) is known in the art, the invention as claimed is deemed to be anticipated, unless such limitations impart structural feature to the composition as claimed.

Jiyoukiyuu (IDS) disclose a composition as claimed as follows (see English abstract below, in particular):

“PRESERVATIVE FOR ANIMAL CELL OR ORGAN AND ITS PRESERVATION

Abstract

PROBLEM TO BE SOLVED: To obtain a preservative for an animal cell or organ capable of making the animal cell or organ preservable for a long period without freezing and freely controlling the proliferation and division of the cell by including a polyphenol as an active component..

SOLUTION: This preservative for an animal cell or organ is obtained by including a polyphenol as an active component. Catechins, tannic acids, etc., which are main ingredients of green tea polyphenols are cited as the polyphenol. The catechins are especially preferred and the catechins consisting essentially of epigallocatechin gallate are more preferred. Cells containing a stem cell, a dermal cell, a mucosal cell, a hepatocyte, an islet cell, a neuron, a cartilaginous cell, an endothelial cell, an epithelial cell, a bone cell, a myocyte or the like isolated from a human or an animal tissue or a sperm, an ovum, a fertilized egg or the like of livestock and fishes are cited as the cell. Skin, a blood vessel, the cornea, the kidney, the heart, a liver, an umbilical cord, intestines, a nerve, a lung, a placenta, pancreas and the like are cited as the organ.”

Since, Jiyoukiyuu (IDS) fully discloses the limitations of the composition as claimed (i.e. a composition comprising a polyphenol such as a catechin (for example, epigallocatechin gallate) as the preferred ingredient, and since said composition is disclosed as being used for the same purposes of organ, tissue or cell preservation, the cited invention is deemed anticipatory over the composition as claimed. The limitation of instant claim 26 (i.e. a "hydroxyl value" of about 2 to about 100) has been taken to be inherent in the disclosed composition comprising a polyphenol such as a catechin, for example, epigallocatechin gallate.

2. Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Masayuki (WO 02/01952 A1; IDS citation B1).

Claims are drawn to a **pharmaceutical composition** (for protecting and preserving an organ, a tissue, or a cell) **comprising** a purified **polyphenol** or a purified mixture of polyphenols (elected species being "**catechin**"; see instant claim 1, in particular).

NOTE: Instant claims 3-21, as recited, are directed to either method steps of administration, or intended use of said composition, the limitations of which have not been given a patentable weight. If the claimed composition comprising catechin (i.e. comprising polyphenol, or a mixture of polyphenols) is known/found in the art, the invention as claimed is deemed to be anticipated, unless such limitations impart structural feature to the composition as claimed.

Masayuki (IDS) discloses a composition as claimed as follows (see WIPO document, English abstract below, in particular):

"Title: PRESERVATION FLUID FOR CELLS AND TISSUES

Abstract: A preservation fluid for cells and tissues, containing a polyphenol as the active ingredient. The fluid may further contain trehalose. The preferable osmotic pressure range is 270 to 450 Osm/l and the preferable pH range is 7 to 8. The preservation fluid is superior to those of the prior art in protective action and can maintain the structures and functions of cells and tissues for a prolonged period."

Since, Masayuki (IDS) fully discloses the limitations of the composition as claimed (i.e. a composition comprising a polyphenol such as a catechin (see Masayuki, that uses a commercial preparation of polyphenol obtained from tea extract as outlined on page 9, and page 12, in particular) as the preferred ingredient, and since said

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composition is disclosed as being used for the same purposes of tissue or cell preservation, the cited invention is deemed anticipatory over the composition as claimed. The limitation of instant claim 26 (i.e. a “hydroxyl value” of about 2 to about 100) has been taken to be inherent in the disclosed composition comprising a polyphenol such as a catechin, or epigallocatechin gallate.

3. Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by N’Guyen (US 5,686,082; [A]).

Claims are drawn to a **pharmaceutical composition** (for protecting and preserving an organ, a tissue, or a cell) **comprising** a purified **polyphenol** or a purified mixture of polyphenols (elected specie being “**catechin**”; see instant claim 1, in particular).

NOTE: Instant claims 3-21, as recited, are directed to either method steps of administration, or intended use of said composition, the limitations of which have not been given a patentable weight. If the claimed composition comprising catechin (i.e. comprising polyphenol, or a mixture of polyphenols) is known/found in the art, the invention as claimed is deemed to be anticipated, unless such limitations impart structural feature to the composition as claimed.

N’Guyen [A] discloses a cosmetic or pharmaceutical composition containing a combination of a polyphenol and a ginkgo extract, wherein said composition is suitable for use in protecting and preserving an organ, a tissue, or a cell (see N’Guyen, abstract, summary of the invention and claimed, in particular), wherein commercial preparations of green tea extracts, or polyphenols such as catechins (for example epigallocatechin gallate; see column 2 last paragraph, example 3 and claims 11-14, in particular) are used and/or disclosed to be suitable for said composition. The limitation of instant claim 26 (i.e. a “hydroxyl value” of about 2 to about 100) has been taken to be inherent in the disclosed composition comprising a polyphenol such as a catechin, for example, epigallocatechin gallate.

4. Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou (US 6,319,523 B1; [B]).

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Claims are drawn to a **pharmaceutical composition** (for protecting and preserving an organ, a tissue, or a cell) **comprising** a purified **polyphenol** or a purified mixture of polyphenols (elected specie being “**catechin**”; see instant claim 1, in particular).

NOTE: Instant claims 3-21, as recited, are directed to either method steps of administration, or intended use of said composition, the limitations of which have not been given a patentable weight. If the claimed composition comprising catechin (i.e. comprising polyphenol, or a mixture of polyphenols) is known/found in the art, the invention as claimed is deemed to be anticipated, unless such limitations impart structural feature to the composition as claimed.

Zhou [B] discloses a composition (for inhibiting oral bacteria) comprising a polyphenol derivative composition comprising catechins (that can be derived from various botanical sources; see abstract, Table 1, columns 2-4, examples 1-2, and claims 1, 4, 5, and 7, in particular). The limitation of instant claim 26 (i.e. a “hydroxyl value” of about 2 to about 100) has been taken to be inherent in the disclosed compositions comprising said polyphenols selected from the group consisting of catechin, resveratrol, and a combination thereof (see Zhou, columns 3-4, and claim 1, in particular).

5. Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Legrand et al (US 6,242,005 B1; [C]).

Claims are drawn to a **pharmaceutical composition** (for protecting and preserving an organ, a tissue, or a cell) **comprising** a purified **polyphenol** or a purified mixture of polyphenols (elected specie being “**catechin**”; see instant claim 1, in particular).

NOTE: Instant claims 3-21, as recited, are directed to either method steps of administration, or intended use of said composition, the limitations of which have not been given a patentable weight. If the claimed composition comprising catechin (i.e. comprising polyphenol, or a mixture of polyphenols) is known/found in the art, the invention as claimed is deemed to be anticipated, unless such limitations impart structural feature to the composition as claimed.

Legrand et al [C] disclose an absorbable prophylactic composition (suitable for protecting and preserving an organ, a tissue, or a cell from ionizing and non-ionizing radiations) comprising solid material extracted from crushed grapes which contains catechin, epicatechin and gallic acid, the catechin and epicatechin being able to be

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intermixed with the gallic acid or to be in a nongalloylated form, wherein catechins are in the form of monomers, or in the form homogeneous or heterogeneous oligomers having different degrees of polymerization (see Legrand et al, abstract, columns 3-4 and claims, in particular). The limitation of instant claim 26 (i.e. a "hydroxyl value" of about 2 to about 100) has been taken to be inherent in the disclosed composition comprising catechins.

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 11/418,421 (common inventor). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of the co-pending application is also directed to a composition (i.e. a cryopreservation medium for

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islets or other tissues for transplantation effective in preventing freeze and thaw injury), comprising epigallocatechin-gallate (i.e. a catechin, applicant's elected specie in the instant application) having a purity of more than 98 % as a cryoprotectant. Since, the two sets of claims are co-extensive in scope, an obviousness-type double patenting (ODP) rejection is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. MURAD (US 6,630,163; issued on Oct. 7, 2003)- Method of treating dermatological disorders with fruit extracts (see entire disclosure).
2. INOUE et al (US 6,210,693 B1; issued on April 3, 2001)- Oil-in water type emulsified composition (see column 7, in particular).
3. TAKEUCHI et al. Characteristics of the OH radical scavenging activity of tea catechins, Journal of Radioanalytical and Nuclear Chemistry, 2007, 272(3): 455-459 (see page 455 and figure 1, in particular).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Satyendra K. Singh/
Examiner, Art Unit 1657